REMARKS/ARGUMENTS

Claims 1-8, 32-39, 43, 50, and 51 are pending in this application. New claims 52 and 53 are added herein, with support found in the original claims. No new matter is entered herein.

Claims 1-8, 32-39, 43, and 50-51 are rejected under 35 U.S.C. §112, first paragraph because the specification allegedly does not reasonably provide enablement for methods of detecting any NF-κB related medical condition in any organism. Applicants respectfully disagree, but amend the claims herein without prejudice and without acquiescence to further the prosecution of this case. Specifically, the pending claims now are directed to detecting Incontinentia pigmenti in a human by analyzing the human NEMO sequence, in some cases the particular sequence of SEQ ID NO:1.

The Examiner appears to suggest in the Office Action on Pages 6-7 that Applicants would need to narrow the claim scope to mutations in human NEMO for Incontinentia pigmenti that are only in coding regions. This is an inappropriate request given both the nature of the invention and the disclosure provided in the specification. The presently pending claims are directed to identifying any mutation in human NEMO, regardless of their location in the gene. One of skill in the art, and particularly in an art traditionally having high skill such as molecular biology, would be able to identify mutations in non-coding regions as well as coding regions, using any standard methods in the art, and certainly those described in Applicants' specification. This is particularly true given that Applicants provided a genomic sequence as SEQ ID NO:1 which comprises both non-coding and coding sequences, and the mechanics of the exemplary methods (PCR; electrophoresis) for identifying mutations do not discriminate between the two types of sequences. Furthermore, on Page 7, Lines 17-25, Applicants disclose a variety of mutations and a variety of locations in the gene where they may be found.

More importantly, Applicants describe in the specification mutations in non-coding sequences. For example, in Example 1 on Page 48, Lines 4-6, Applicants disclose a mutation within the stop codon of the message. A stop codon is a non-coding sequence, given that it does not have a corresponding tRNA and encodes no corresponding amino acid residue.

More particularly, although the Examiner states in the Office Action on Page 6 that "the majority of alterations in SEQ ID NO:1 detected by the applicants are the result of a deletion in the C terminus of the human NEMO," this deletion is the result of a mutation (a duplication) in intron 3 (see Example 3, particularly Page 54, Lines 13-14; FIG. 3E; and Page 60, Lines 17-19).

Even if Applicants did not disclose in the specification mutations in the non-coding sequences related to Incontinentia pigmenti, it would be inappropriate to require Applicants to amend to such, given that there are examples known in the art at the time of filing of mutations in non-coding sequences related to genetic disease (see, for example, Shahbazian and Zoghbi, 2001; Chaturvedi et al., 2001, both of which are submitted herewith in a Supplemental IDS). Therefore, it would not be undue experimentation to identify mutations in non-coding regions associated with Incontinentia pigmenti.

The Examiner also states on Page 6 of the Office Action that "only primer pairs which amplify coding exons were able to detect mutations in SEQ ID NO:1 which correlate with loss of NF-kB activity." This is untrue, given that Example 11 describes PCR primers to detect the intron 3 rearrangement mutation. Even if this were true, it would not require undue experimentation to use other primer pairs, such as those disclosed by Applicants, to detect mutations, such as by methods disclosed in Examples 1-3, 8, and 11, and then analyze a correlating loss of NF-kB activity, such as by methods disclosed in Examples 4 and 5.

Therefore, Applicants teach identification of mutations in non-coding sequences, and this argument by the Examiner is not germane.

Therefore, Applicants assert that it is unnecessary and inappropriate to require the claim scope be directed to only exon coding sequences.

Claims 50 and 51 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification to convey to a skilled artisan that the inventors had possession of the claimed invention at the time of filing. Applicants respectfully disagree but amend without prejudice and without acquiescence the claims by cancelling claim 50 and amending claim 51 to further the prosecution of this case. Namely, claim 51 now relates specifically to human NEMO genes.

Applicants assert that the claim as now pending is described in such a matter that one of skill in the art would know that the inventors had possession of a human NEMO gene at the time of filing. That is, one of skill in the art would know that disclosure of utilization of SEQ ID NO:1 in the specification was sufficient to describe a human NEMO gene and therefore sufficient to demonstrate possession at the time of filing. Additional species of human NEMO, such as mRNA sequences (for example, AF091453 published in GenBank in June 1999), would be both unnecessary and non-optimal, given that written description of human NEMO is already provided in SEQ ID NO:1 and that mutations could and do occur in non-coding regions (see above).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicants believe no fee is due with this response except for the fee for the Supplemental IDS. However, if another fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01961US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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